

**REMARKS**

The Pending Claims:

Before entry of the preceding Claims 12-30 and 56-79 are pending in this application. Claims 12-30 and 56-79 are directed to a method of treating irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, attention deficit/hyperactivity disorder, an autoimmune disease, or Crohn's disease.

The Office Action and Applicant's Response

Examiner Navarro acknowledged that Applicant's amendment, received February 10, 2003 (Paper No. 19; mailed by Applicant on February 3, 2003) has been received and entered.

In the current amendment, Claim 15 has been cancelled, without prejudice, as being a duplicate of Claim 20, as originally filed.

In the pending Office Action, the Examiner stated that all grounds of rejection in the Office Action mailed November 13, 2002 are withdrawn.

The Examiner acknowledged that the specification is "enabling for methods of treatment of bacterial overgrowth comprising detecting small intestinal bacterial overgrowth and at least partially eradicating the bacterial overgrowth."

However, the Examiner asserted a new ground of rejection for Claims 12-30 and 56-79, under **35 U.S.C. § 112, first paragraph**, because the specification purportedly lacks enablement for the scope of the claims as to "treatment of the autoimmune disease systemic lupus erythematosus [SLE]." The examiner stated:

Way (Current Surgical Diagnosis & Treatment, 9th Edition, 1991, page 1083) sets forth that systemic lupus erythematosus is an autoimmune disease in which the presence of anti-DNA antibodies are diagnostic. (See page 1083). In other words, a patient's own immune system is attacking its own cells. Applicant's specification sets forth in Example 5, 15 patients which had been diagnosed with SLE, and of these 15 patients, 13 had bacterial overgrowth, as indicated by LBHT. Applicant's specification further sets forth of administering neomycin to these patients, and reports decreased joint pains, gas and fatigue in 4 patients. However, the antibiotic which would certainly eradicate the bacterial overgrowth and lead to decreased gas, does not "treat" systemic lupus erythematosus. The presence of anti-DNA antibodies which would continue to react with the patient's own DNA, would remain unchanged and unaffected. The disease itself remains

unaffected. Applicants have effectively treated the bacterial overgrowth, however, this is not commensurate in scope with the treatment of SLE, as set forth in the instantly filed claims.

In response, Applicant has overcome the ground of rejection by herein amending Claims 12, 67, and 70. Independent Claim 12 has been amended to delete the recitation of “an autoimmune disease selected from the group consisting of . . . systemic lupus erythematosus.” In independent Claims 67 and 70, the recitation of “an autoimmune disease” has been limited to “multiple sclerosis,” no longer reading on the autoimmune disease systemic lupus erythematosus.

The ground of rejection being overcome by the amendments to Claims 12, 67, and 70, Applicant respectfully requests the Examiner to withdraw the rejection of Claims 12-30 and 56-79.

In view of the amendments to independent Claims 12, 67, and 70, which it is believed are allowable, Applicant has added new Claims 80-99, which are dependent from amended Claims 12, 67, and 70, respectively, and are each more narrowly directed to only a single one of the suspected diagnoses recited in the preambles of their respective independent claims.

**CONCLUSION**

In view of the above amendments and remarks, it is submitted that this application is now ready for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney at (213) 896-6665.

Respectfully submitted,

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